

REMARKS

Favorable reconsideration of this application, in light of the preceding amendments and following remarks, is respectfully requested.

Claims 1, 3, 5-7 and 10 are pending in this application. Claims 1 and 3 are amended and claims 2 and 4 have been cancelled. Claims 1 and 3 are the independent claims.

Applicants note with appreciation the Examiner's acknowledgement that certified copies of all priority documents have been received by the U.S.P.T.O. Action, summary at 12.

Example Embodiments of the Present Application

Example embodiments recite a kit for use in the treatment of lupus, multiple sclerosis, rheumatoid arthritis, rheumatism, osteoporosis, and asthma in humans or tail and mane eczema in horses. Both lupus and eczema are disorders that manifest themselves through abnormalities of the skin. Example non-limiting embodiments of this feature are discussed, for example, in paragraph [0031] of the instant specification.

As is illustrated in paragraph [0031] of the present application, the kit is used to treat lupus and/or tail or mane eczema in mammals, for example, horses. Example 1 illustrates that treatment of a patient with the kit according to example embodiments, followed by exposure to sunlight, did not lead to inflammation whereas such an effect did occur before treatment. The kit lifts the system-reticulo-endothelial blockade and improves biofeedback, thereby leading to an overall improvement in the horse's physical condition.

Rejections under 35 U.S.C. § 103

Flynn, Widy-Tyszkiewicz, Singh, McClung, Brandes and Marchioni

Claims 1-7 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of Flynn (The herbal management of stress, Australian journal of medical herbalism, 1996: 8 (1): 15-18), Widy-Tyszkiewicz et al (A randomized double blind study of sedative effects of phytotherapeutic containing valerian, hops, balm and motherwort versus placebo, Herba polonica, (1997) Vol. 43, No. 2, pp. 154-159), Singh et al (Therapeutic potential of Kava in the treatment of anxiety disorders, CNS drugs 2002: 16 (11): 731-743), McClung (US 6579543), Brandes (WO 01/34170) and Marchioni (US 7,087,250). Applicants respectfully traverse this rejection for the reasons detailed below.

The Examiner states that claims 1 and 3 relate to a kit comprising six individual plant extracts that would be obvious over the cited prior art, constituted by Flynn, Widy-Tyszkiewicz and Schminda, Singh and Singh, McClung, Brandes and Brandes, and Marchioni. Applicants respectfully disagree.

Applicants respectfully submit that Flynn discloses the use of several herbs in the management of stress. Although herbs such as *Avena sativa*, *Glycyrrhiza glabra* and *Eleutherococcus senticosus* are disclosed, Flynn fails to provide one of skill in the art what could or would be an effective unit dose of any of these three individual herbs. The cited prior art, specifically McClung, discloses a herbal composition which can comprise a plethora of different herbal extracts which as individual constituents apparently all have widely varying effective amounts. For example, the effective amount for willow bark extract ranges from as low as 0.01 % up to 10%, whole leaf aloe vera can comprise from 55 up to 70%, while the presence of a combination of six herbal extracts should be present in a concentration of 0.01 to 1% (cf. col. 6, lines 59-63; col 4, lines 11-15 and col 8, lines 37-45, respectively). From these disclosures,

Applicants submit that without at least some sort of guidance regarding an effective dose, there cannot be any reliance on routine experimentation by one skilled in the art to arrive at the teachings as recited in claims 1 and 3.

Moreover, Flynn does not provide any information on which part(s) of these herbs could be useful. Claims 1 and 3 recite the roots of *Glycyrrhiza glabra*. Applicants submit that it is well known in the field of herbal medicines that different plant organs or plant tissues can comprise different active ingredients. McClung for example mentions the presence of many distinct substances in leaves, roots and flowers of the dandelion plant (cf. col. 11, lines 46-58). The relevance of such selection becomes clear from the notion that linden flowers are known as blood circulation promoters, whereas linden is known for the entirely different purpose of an antidepressant (compare col. 3 lines 29 and 41 to col. 3, lines 47 and 57). As Flynn is completely silent about the usefulness of the roots of this herb, Applicants submit that Flynn does not teach or suggest a unit dose of 100 -1000 mg roots of *Glycyrrhiza glabra/gan cao* as recited in amended claims 1 and 3.

Further, Applicants submit that none of the prior art makes any suggestion or provides any motivation to combine the specific herbal extracts as recited in claims 1 and 3. One skilled in the art that is interested in providing a herbal extract which could be used as an anti-stress agent, would likely use any of the individual herbs of each reference which have been disclosed as being useful in treating stress. Therefore, Applicants submit that one skilled in the art would not have combined the herbs as recited in claims 1 and 3 merely based on the notion that these herbs are disclosed for an alleged similar purpose. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the

prior art or knowledge available in the art also suggests the desirability of the combination.¹

There are three possible sources for a motivation to combine references: (1) the nature of the problem to be solved, (2) the teachings of the prior art, and (3) the knowledge of persons of ordinary skill in the art.² In the present Office Action, the Examiner alleges that the motivation to combine the teachings of the cited references is to provide the known benefit of anti-stress activity and that one skilled in the art would have had a reasonable expectation that the combination of these compounds would have been additively beneficial for anti-stress activity.

However, the Examiner is using impermissible hindsight reconstruction to reject the claims. The Federal Circuit has noted that the PTO and the courts "cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention,"³ and the best defense against hindsight-based obviousness analysis is the rigorous application of the requirement for a showing of a teaching or motivation to combine the prior art references. Without access to the present invention, Applicants submit that there would neither be any motivation nor any inclination of one skilled in the art to combine these herbs in order to render obvious claims 1 and 3. None of the references teach that the combination of the herbs would allow for more anti-stress activity, and the Examiner cannot support this assertion without any evidence.⁴

¹ *In re Mills*, 916 F.2d 680 (Fed. Cir. 1990).

² *In re Rouffet*, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998)

³ *In re Fine*, 5 USPQ2d 1780, 1783 (Fed. Cir. 1988)

⁴ See MPEP 2144.09 ("The presumption of obviousness based on a reference disclosing structurally similar compounds may be overcome where there is evidence showing there is no reasonable expectation of similar properties in structurally similar compounds").

With regard to Widy-Tyszkiewicz and Schminda, Applicants would admit that a commercially available “anti-stress tablet” is disclosed, but this tablet includes both motherwort and valerian root which, according to McClung, are compounds having anti-stress activity (cf. McClung, column 3, lines 46-60). Also Singh mentions valerian to be efficacious in the management of stress (cf. middle part of the right column of page 733 of this document). However, there is no disclosure in the cited art that the other two components indeed also have anti-stress properties and, more importantly, what the contribution of the four individual herbal components would be if they were used separately. Therefore, Applicants submit that there cannot be any reliance on routine experimentation by one skilled in the art to arrive at the teachings as recited in claims 1 and 3.

Also, there is no reason to assume, without knowledge of the present invention, why one skilled in the art would be inclined to choose roots out of a whole range of possible plant organs or tissues. The list of plant parts may be finite, but appears more extensive than just root, stem, flower, bud, leaves, etc. One can imagine a laundry list of plant organs or tissues from which the skilled person would need to select the roots of such a plant while, without any motivation, the skilled person would not have any inclination to do so. The only motivation for selecting the roots of such plant appears to be derivable from the present invention and without access thereto, the skilled person would not make this selection.

A similar reasoning also applies to the disclosure of Marchioni who discloses the use of cat's claw bark but not the root thereof. Even though the bark may be comprised by the root, Applicants submit that these different organs comprise distinct compounds which may have completely different fields of usage, such as linden flowers which are known as blood circulation promoters, whereas linden is known for the entirely different purpose as antidepressant. Thus, absent any suggestion, the

skilled person would not contemplate using *Uncaria tomentosa* roots instead of the bark thereof.

Moreover, in light of the fact that the anti-stress tablet as disclosed includes four herbs in an apparently effective ratio, Applicants submit that one skilled in the art would not have been motivated to use only one of these herbal extracts for the development of a completely new kit as recited in claims 1 and 3.

Regarding the use of *Piper methysticum*, Singh does not provide any suggestion to combine this herb with any other herb, let alone the herbs as recited in claims 1 and 3. Furthermore, based on Singh, one skilled in the art would not have a reasonable expectation of success to arrive at the claimed subject-matter as Singh discloses that “one of the **unresolved problems** in considering the effects of kava is the correlation between the pharmacological actions of kavalactones and their plasma concentrations” (cf. upper part right column of page 734. Emphasis added). Apparently, there is no correlation between plasma concentration and pharmacological activity which would allow the skilled person to rely on mere routine experimentation to achieve the effects for which *Piper methysticum* can be used.

In addition, Singh discloses that “both pharmacokinetic and pharmacodynamic properties were enhanced synergistically when the kavalactones were given together rather than separately” (cf. upper part of right column of page 734). It is well known in any art that synergistical effects are difficult if not impossible to predict or control. As such, Applicants submit that one skilled in the art would not be interested in developing a kit which comprises six herbal extracts as recited in claims 1 and 3, as there are no teachings of advantages that make this combination desirable.

As further evidence, McClung teaches that “[a]n optimum concentration of kava kava extract is about 0.1 % of the composition” (cf. column 8, lines 8-9) whereas Singh teaches that from 100 mg to 300 mg kava extracts may be used. If 100 mg kava would

be 0.1% of a composition, the composition taught by McClung would amount to 100 – 300 grams (about 3.5 to 10.5 ounce), assuming weight percentages. Thus, there is no guidance to be found in the prior art on record which the one skilled in the art could use to start his or her routine experimentation to arrive at the compositions as claimed in amended claims 1 and 3. Applicants also submit that as the prior art teaches contradictory technical teachings on the use of kava, one of skill in the art could not have a reasonable expectation of success to arrive at the compositions as claimed in amended claims 1 and 3.

McClung discloses a composition for topical application to an animal's skin for relief from a variety of symptoms caused by medical conditions or physical injuries which "composition may further include an effective amount of at least one compound having antidepressant/anti-anxiety/anti-stress activity" (cf. column 3, lines 45-55). Next, a total of 40 different compounds, extracts or ingredients are disclosed which could be used for this purpose. Applicants submit that one of ordinary skill in the art would not be induced to focus on black horehound from this extensive list of apparently equally suitable ingredients without any guidance to do so. And even if the skilled person would focus on black horehound from this list, one skilled in the art would still not be motivated to combine this herb with the other herbal extracts as claimed in amended claims 1 and 3.

Further, there are no effective amounts taught for these ingredients disclosed in McClung. Regarding ingredients for which such an effective amount is disclosed, these effective amounts range from about 0.01% to up to 15% or even 70% (as mentioned above, or cf. column 4, line 47 and column 8, line 41). The effective amount of yet another of these ingredients, i.e. Roman chamomile, feverfew or St. John's wort, may be as low as about 0.01% to about 1% of the composition, with an optimum of 0.1% (column 8, lines 37-45). Therefore, Applicants submit that there cannot be any

reliance on routine experimentation by one skilled in the art to arrive at the teachings as recited in claims 1 and 3.

Brandes discloses a phytotherapeutic composition which "has a broad area of use as health product. The product furthers the general feeling of well being, increases stress tolerance..." (cf. abstract). According to page 1, lines 25-30, it is already sufficient for achieving improved resistance to stress using a composition which contains *Allium sativum*, *Junglans regia*, *Echinacea purpurea* and *Viola tricolor*. In fact, there is no disclosure in Brandes that *Uncaria tomentosa* has any anti-stress properties and would be added for providing or even providing the slightest contribution to such an effect. Instead, Brandes discloses that the basic phytotherapeutic composition may further comprise *Uncaria tomentosa* only if one wishes to increase immunity and resistance to infections (cf. page 5, lines 21-22). Brandes thus does not even correlate *Uncaria tomentosa* to the purpose of reducing stress.

This is also true for Marchioni wherein it is only mentioned in ambiguous terms that cats claw bark is known to "enhance stress reduction and inflammation" as was noted by the Examiner. However, Sandoval teaches that cats claw bark can be used against (oxidative) stress and inflammation. Consequently, the mentioning in Marchioni that the bark of cats claw is able to "enhance stress reduction and inflammation" may apply and cannot be excluded to apply to these findings reported by Sandoval. As it was found to be convincing that oxidative stress is different from mental forms of stress, it is submitted that there is still no unambiguous disclosure in the prior art of record that *Uncaria tomentosa* can be used for the same purpose of diminishing mental forms of stress.

Applicants submit that none of the prior art documents suggest using any of these individual herbal extracts for these disorders as recited in claims 1 and 3, and

that the cited art discourages one skilled in the art to use these herbs for the treatment of disorders that manifest themselves through the skin.

For example, Singh discloses that “the adverse effects attributed to kava [i.e. *Piper methysticum*] use were considered mild or negligible, **except for the occurrence of skin lesions**” (cf. lowest paragraph of page 731, emphasis added). Furthermore, Singh states that it is **unquestioned** that a disorder which has been termed “kava dermopathy” can occur from excessive kava intake (cf. second section of §4.4.4, page 739) and “[i]ts major adverse effect appears to be a scaly skin condition” (cf. lower part, left column, page 740).

Thus, Singh clearly teaches that intake of kava (i.e. *Piper methysticum*) is correlated with occurrence of skin problems. Therefore, Applicants submit that one skilled in the art would not contemplate using kava for treatment of a disorder which manifests itself through the skin, when the teachings of Singh state that kava is known to cause skin disorders.

For all of the above reasons, Applicants respectfully submit that neither Flynn, Widy-Tyszkiewicz, Singh, McClung, Sandoval nor the combination thereof teach or suggest a kit for use in the treatment of lupus, multiple sclerosis, rheumatoid arthritis, rheumatism, osteoporosis, and asthma in humans or tail and mane eczema in horses including the six compositions and unit doses thereof as recited in claims 1 and 3.

The Applicants, therefore, respectfully request that the rejection to Claims 1 and 3 under 35 U.S.C. § 103(a) be withdrawn.

Claims 2-7, dependent on independent claims 1 and 3, are patentable for the reasons stated above with respect to claims 1 and 3 as well as for their own merits.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection to independent claims 1 and 3 and all claims dependent thereon.

CONCLUSION

In view of the above remarks and amendments, the Applicants respectfully submit that each of the pending objections and rejections has been addressed and overcome, placing the present application in condition for allowance. A notice to that effect is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to contact the undersigned.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicant(s) hereby petition(s) for a two (2) month extension of time for filing a reply to the outstanding Office Action and submit the required \$245 (small entity) extension fee herewith.

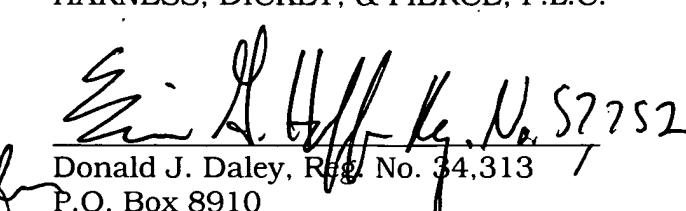
Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Erin G. Hoffman, Reg. No. 57,752, at the telephone number of the undersigned below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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